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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/192,579	11/17/1998	FRANCO MENOZZI	960-34	9973

7590 01/09/2002

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/192,579	Applicant(s) Menozzi et al
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *29October2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *56-81* is/are pending in the application.

4a) Of the above, claim(s) *71-81* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *56-70* is/are rejected.

7) ☒ Claim(s) *57, 59, and 62* is/are objected to.

8) ☒ Claims *56-81* are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicants' Response to Restriction, received 29October2001, paper#18, is acknowledged. Claims 30-35 have been canceled without prejudice. Claims 64 and 66 have been amended.

Applicants elect, with traverse, invention I, claims 30-35 and 56-70, drawn to polypeptides, classified in class 424, subclass 248.1.

No reasons for traversal being put forth, the restriction requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 71-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 56-70 are under consideration.

Drawings

3. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

4. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Neither Figure 7(or it brief description) nor Figure 10(or its brief description) recite the necessary sequence identifiers.Appropriate correction is required.

5. The Brief Descriptions of Figures 1 and 5 are objected to because: 1) the brief description does not detail that there are acturally Figures are 1A and 1B, 2) the brief description does not detail that there are acturally Figures are 5A and 5B.

Specification

6. The disclosure is objected to because of the following informalities:

a) page 6, lines 15-16 describe the bars in Figures 1A dnd 1B incorrectly; the description is that CHO cells are "grey bars", but Figure 1B indicates "open bars" and that macrophages are "black bars", but Figure 1B indicates "speckled bars",

b) page 9, line 23, should "globules" be "erythrocytes"?,

c) page 10, line 9, "he" should be "the",

d) page 11, line 8, what is meant by "immunitary serum"?,

e) page 13, line 12, it is unclear what is meant by the crossthrough "(23)",

f) page 19, line 7, it is unclear what is meant by the crossthrough "25",

Appropriate correction is required.

7. M.P.E.P. §2422.03, paragraph eight, requires that a sequence identifier ("SEQ ID NO:X") must be used when a sequence occurs in the text of the specification or claims. The sequence listings in the instant specification does not recite the necessary sequence identifiers. Appropriate correction is required.

Claim Objections

8. Claim 57 is objected to because the claim lists a sequence but does not recite the necessary sequence identifier required under M.P.E.P. §2422.03, paragraph eight. Appropriate correction is required.

9. Claims 59 and 62 are objected to because "recognised" should be "recognized".

Deposit Requirement

10. The specification lacks deposit information for the monoclonal antibodies listed as "4057 D2" and "3921 E4". Because it is not clear that monoclonal antibodies possessing the properties of "4057 D2" and "3921 E4" are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of "4057 D2" and "3921 E4", a suitable deposit for patent purposes is required. Without a publicly available deposit of the above "4057 D2" and "3921 E4", one of skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the specific monoclonal antibodies "4057 D2" and "3921 E4" is an unpredictable event. Note that the best mode is not satisfied by a written disclosure unless the exact embodiment is reasonably reproducible from that disclosure. If reproducibility of the "4057 D2" and "3921 E4" is not established, failure to deposit "4057 D2" and "3921 E4" would result in concealment of the best mode contemplated by applicant for carrying out the invention. In re Sherwood, 615.2d 809, 204 USPQ 537 (CCPA 1980).

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has

authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each nation. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §§1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) the name and address of the depository,

2) the name and address of the depositor,

3) the date of deposit,

4) the identity of the deposit and the accession number given by the depository,

5) the date of the viability test,

6) the procedures used to obtain a sample if the test is not done by the depository, and

7) a statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the "4057 D2" and "3921 E4" described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundeck, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §§1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 56-59 and 65 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn merely to a proteinic mycobacterial antigen comprising peptide sequences. There is no recitation of "isolation" or "purification". Thus, the composition reads on whole mycobacteria occurring in nature.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 59 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of "4057 D2" and "3921 E4" as the sole means of identifying the claimed monoclonal antibodies renders the claims indefinite because "4057 D2" and "3921 E4" are merely laboratory designations which do not clearly define the claimed product since different laboratories may use the same laboratory designation to define completely distinct monoclonal antibodies.

16. Claims 56-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 56, 60, 63, and 66 recite that the composition comprises a component of a sequence shown in Figure 10. This in indefinite as Figure 10 can be amended, thus amending the claims. It is recommended that the claims state by SEQ ID Number which sequences are being claimed. For example, the claims may recite: SEQ ID NO:1, residues 16-56.

Also, the claims are drawn to "the C-terminal portion of the peptide sequence" and "more particularly all or a portion of the last 50 amino acids". However, it is unclear what are the metes and bounds of which residues constitute the entire "C-terminal" and therefore what constitutes "all or a portion".

It is unclear what is meant by said antigen "being involved" in the adhesion of mycobacteria. The specification recites that HBHA is a peptide sequence "enabling mycobacteria to adhere to host cells". The specification does not define "involvement".

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 56-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Menozzi et al (*Abstracts of the General Meeting of the ASM*, 95(0):193, abstract B-159)

The claims are drawn to a protein/peptide obtainable from a mycobacteria which is involved in adhesion of mycobacteria to epithelial cells.

Menozzi et al teach the isolation of the claimed invention from mycobacteria, i.e., BCG and *M. tuberculosis*. The amino acid sequence is an inherent characteristic of the peptide/protein, in the absence of evidence to the contrary.

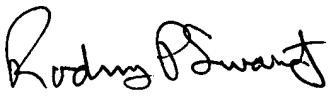
Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

January 9, 2002